DXC (URIC) URIC ACID

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PURPOSE

To provide instructions for the quantitative determination of uric acid on the DXC 600/800.

PRINCIPLE

URIC reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems Multi Calibrator, is intended for the quantitative determination of Uric Acid concentration in human serum, plasma or urine.

BACKGROUND

Clinical Significance

Uric acid measurements are used in the diagnosis and treatment of numerous renal and metabolic disorders, including renal failure, gout, leukemia, psoriasis, starvation or other wasting conditions, and of patients receiving cytotoxic drugs.

Methodology

URIC reagent is used to measure the uric acid concentration by a timed-endpoint method. Uric acid is oxidized by uricase to produce allantoin and hydrogen peroxide. The hydrogen peroxide reacts with 4-aminoantipyrine (4-AAP) and 3,5-dichloro-2-hydroxybenzene sulfonate (DCHBS) in a reaction catalyzed by peroxidase to produce a colored product.

The SYNCHRON® System(s) automatically dilutes urine samples and proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 25 parts reagent for serum or plasma and one part diluted sample to 25 parts reagent for urine. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of uric acid in the sample and is used by the System to calculate and express the uric acid concentration.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
J-F-CH0826	DXC 800 Calibrators
J-F-CH1940	DXC 800 Analytical Measurement Range
M-F-CH0820	Chemistry Controls
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum or plasma are the preferred specimens. Freshly collected urine may also be used for testing. Acceptable anticoagulants are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Whole blood is not recommended for use as a sample.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum or plasma should be stored at +2°C to +8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.

3. It is recommended that urine assays be performed within 2 hours of collection. For timed specimens, the collection container should be kept at room temperature. Sodium hydroxide (NaOH) should be added to keep urine alkaline.

Sample Type	Volume	Sample Stability
Plasma/Serum	0.5mL	• 8 hours at 18-26°C • 48 hours at 2-8°C • After 48 hours, freeze at -15 to -20°C
Urine	0.5 mL	• Test within 2 hours of collection • Timed specimens are kept at RT • For timed urine collections, adjust an aliquot to pH >7 with 5% NAOH • Do not use acidified urine

Sample Preparation

Sample preparation is not required. Urine samples are diluted (1:10) automatically by the system using the DIL1 cartridge.

Criteria for Unacceptable Specimens

See Specimen Rejection/Cancellation Protocol

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two URIC Reagent Cartridges (2 x 300 tests), kit #442785

Serum/Plasma Volume per Test	
Sample Volume	12 µL
Ordac sample volume	6 uL
Total Reagent Volume	300 µL
Cartridge Volumes	A 270 µL B 30 µL

Urine Volume per Test	
Sample Volume	20 µL
Diluent (DIL1) Volume	180 uL
Diluted Sample Volume	12 uL
Total Reagent Volume	300 µL
Cartridge Volumes	A 270 µL B 30 µL

Reactive Ingredients	
4-Aminoantipyrine	0.85 mmol/L
3,5-Dichloro-2-hydroxy-benzene sulfonate	3.4 mmol/L
Uricase	240 IU/L
Horseradish peroxidase	961 IU/L.

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

URIC reagent, when stored unopened at +2°C to +8°C, will remain stable until the expiration date printed on the cartridge label. Once opened, the reagent cartridge is stable for 30 days at +2°C to +8°C. Do not use beyond the manufacturers expiration date. DO NOT FREEZE.
DIL 1 stored unopened at room temperature is stable until the expiration date indicated on each cartridge. Once opened, DIL 1 is stable for 60 days on instrument or until the expiration date, if sooner.

CALIBRATION

Calibrator Required

SYNCHRON® Systems Multi Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

If unopened, the SYNCHRON® Systems Multi Calibrator should be stored at -15°C to -20°C until the expiration date printed on the calibrator bottle. Opened calibrators that are resealed and stored at +2°C to +8°C are stable for 20 days. Do not use beyond the manufacturers expiration date.

Calibrator Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the URIC reagent cartridge must be calibrated every 14 days or with each new bottle of reagent and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

3. This assay has within-lot calibration available. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions for Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. If necessary, load the reagent onto the system.

2. After reagent load is completed, calibration is required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

1. If plasma is the sample of choice, the following anticoagulants were found to be compatible with this method based on a study of 20 healthy volunteers:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Ammonium Heparin	14 Units/mL	No Significant Interference[b]
Lithium Heparin	14 Units/mL	No Significant Interference
Sodium Heparin	14 Units/mL	No Significant Interference

2. The following anticoagulants were found to be incompatible with this method:

Anticoagulant	Level Tested for In Vitro Interference	Average Plasma-Serum Bias (mg/dL)
Potassium Oxalate/ Sodium Fluoride	2.0 / 2.5 mg/dL	-0.7

PERFORMANCE CHARACTERISTICS

Reference Range

Sample Type	Gender/Age	Range
Serum / plasma	Male 0-17 years	2.0 - 5.5 mg/dL
Serum / plasma	Male 18-150 years	3.2 - 8.6 mg/dL
Serum / plasma	Female 0-17 years	2.0 – 5.5 mg/dL
Serum / plasma	Female 18-150 years	2.2 - 7.1 mg/dL
Urine, timed		*250 – 750 mg/day
Urine, random		N/A

*****Reference range for urine not established by this laboratory. Reference comes from literature.

Analytic Range

The SYNCHRON® System(s) method for the determination of this analyte provides the following analytical range:

Sample Type	Conventional Units
Serum or Plasma	0.5 – 12.0 mg/dL
Serum or Plasma (ORDAC)	9.0 – 21.0 mg/dL
Urine	5 – 120 mg/dL

Samples with concentrations exceeding the high end of the analytical range should be rerun with ORDAC enabled or diluted with saline and reanalyzed.

Reporting results outside of analytical range

Lower limit of range: serum / plasma	0.5 mg/dL	Results below 0.5, report as <0.5 mg/dL
Upper limit of range: serum / plasma	21.0 mg/dL	Results >21.0 should be diluted with 0.9% saline, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >42 should be reported as >42 mg/dL.
Lower limit of range: urine	5 mg/dL	Results below 0.5, report as <5mg/dL

Upper limit of range: urine	120 mg/dL	Results >120 should be diluted with 0.9% saline starting with X2, reanalyzed and dilution factor applied. The maximum allowable dilution is X5. Results >600 should be reported as >600 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for URIC determination is 0.5 mg/dL for serum or plasma, and 5.0 mg/dL for urine.

LIMITATIONS

None identified.

Interferences

1. The following substances were tested for interference with this methodology:

Substance	Source	Level Tested	Observed Effect
Bilirubin (Total)	Porcine	2.6mg/dL DBIL 5.2 mg/dL TBIL INDEX of 4	-0.4@2.6mg/dL URIC
			-1.0@8.7mg/dL URIC
Bilirubin (Unconjugated)	Bovine	10 mg/dL	≤±0.7 mg/dL or 10%
Hemoglobin	RBC hemolysate	300 mg/dL INDEX of 9	≤±0.7 mg/dL or 10%
Lipemia	Human	Intralipid 160 mg/dL INDEX of 4 Airfuge recommended	≤±0.7 mg/dL or 10%
Albumin	Human Cohn Fraction V[j]	8 g/dL	-0.5 mg/dL
Ascorbate (Serum)	SIGMA[k]	1.5 mg/dL	-0.3 mg/dL
Ascorbate (Urine)	SIGMA	20 mg/dL	+3.0 mg/dL

2. Interferences should also be suspected from the following substances: Theophylline metabolites (1,3-dimethyluric acid and 1-methyluric acid), catecholamines, methylene blue, sulfasalazine, EDTA, sodium fluoride, and other reducing agents.

3. Refer to References (10,11,12) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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